

REMARKS

A. Status of the Claims

Claims 1-14, 30-34 and 182-183 were pending at the time of the Action. Claims 2, 10-14 and 182-183 have been amended herein to correct clerical errors. Some of the amendments were submitted in Applicants' response to final Office Action, but were refused entry in the case. Amendments were also submitted in an amendment under 35 U.S.C. §116, but these are also believed to have not been entered in the case. Claims 1-14, 30-34 and 182-183 are presented herein for reconsideration. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

B. Formalities

1.) The Action has objected to the drawings. In response, Applicants note that new drawings are being submitted herewith. It is believed that the objection is now moot in light of the submission.

2.) The Action objects to the list of references in the specification as not being a proper information disclosure statement (IDS). In response, Applicants note that an IDS has been filed in compliance with 37 C.F.R. §1.97 and 37 C.F.R. §1.98. Applicants have not alleged that the list in the specification is an IDS. Removal of the objection is thus requested.

3.) The Action objected to the IDS filed 10/1/99 as failing to comply with 37 C.F.R. §1.98(a)(3) because the IDS does not include a concise explanation of the relevance of reference B1 (PCT WO 99/06038), which is not in English. In response, Applicants note that the reference includes an English abstract and, accordingly, no translation is required. Removal of the objection is thus respectfully requested.

4) Claims 2 and 10-11 are objected to under 37 C.F.R. §1.821(d) for failing to recite SEQ ID NOs in the claims. The claims have been amended to recite the corresponding SEQ ID NOs and thus the objection is believed to now be moot.

C. **Prior Art Rejections Under 35 U.S.C. §102 and 35 U.S.C. §103**

The prior art rejections under 35 U.S.C. §102 and 35 U.S.C. §103 set forth in the final Office Action were maintained. The Action has indicated that the prior art rejections have been maintained due to the use of the word “about two-months” in the claims. Specifically, the Action appears to acknowledge that the prior art does not teach PAGs that are detectable early and undetectable at two-months post-partum, but indicates that due to modification of “two-months” by the term “about,” the claim reads on a prior art PAG detectable as few as 80 days post-partum. Applicants respectfully traverse.

Claim terms must be given their plain meaning unless applicants define them otherwise. That is, terms must be read as they would be interpreted by those of ordinary skill in the art. *In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983). In Applicants’ response to the final Office Action, evidence was submitted of the plain meaning of “about” in the form of two dictionary definitions. In particular, the Encarta™ online dictionary (<http://dictionary.msn.com>) gives the meaning of the relevant usage of the word as a preposition as “approximately: close to in number, time, or degree”. Appendix A. The relevant definition of “about” from the online version of the Merriam Webster’s Collegiate Dictionary™ (<http://www.m-w.com>) is “reasonably close to.” Appendix B. Therefore, an interpretation of “about two months” to include 80 days does not fit the plain meaning of “about.” Even assuming that BoPAGs are taught in the prior art that are undetectable as early as 80 days post-partum, this number is neither “close to in number,

time, or degree” nor “reasonably close to” two-months. 80 days is nearly three weeks longer than two-months. It is 33% more than 60 days.

One of skill in the art would thus recognize that 80 days does not comport with the meaning of the claims. This is particularly so when one considers that the claims must be read in the context of the relevant technical field and specification. First, one of skill in the art would understand that “about,” “close to in number, time, or degree” or “reasonably close to” in a precise technical field such as molecular biology does not permit a 33% deviation in time. Secondly, a reading of the specification demonstrates that this reading is inconsistent with the description. As indicated in the Related Art section of the specification, prior techniques of pregnancy detection had a disadvantage in that the PAG (e.g., boPAG1) can be detected at 80-100 days postpartum, thereby “compromising pregnancy diagnosis in cows bred within the early postpartum period.” This is a problem because cows are customarily rebred within 2-3 months after calving (see last two sentences of the first full paragraph on page 233 of Roberts et al., 1995). Therefore, in view of the well known meaning of “about” and the teaching of the specification, one of skill in the art would understand that “about two-months” does not read on 80 days.

Two cases are cited in support of the rejection. First, *Kolene Corporation v. Motor City Metal Treating, Inc.*, 307 F. Supp. 1251, 1261, (E.D.Mich.1969), is cited as holding that “about” is warning that exactitude is not claimed but rather that there is some range from a chemically operative lower limit to a commercially imposed (for commercial reasons) upper limit. However, Applicants note that this is a 1969 case from the District Court of the Eastern District of Michigan, Southern Division. Similarly, the second case, *General Foods Corp. v. Perk Foods Co.*, 283 F. Supp. 100 (N.D. Ill. 1968), is a 1968 Northern District of Illinois case and was

reversed by the 7th Circuit Court of Appeals. Thus, neither case is binding precedent on the Board of Patent Appeal and Interferences or the Court of Appeals for the Federal Circuit. Further, no basis has been presented to show the relevance of the cases to the instant facts or set of claims.

Cases that are precedential upon the PTO have found the term "about" to be fully clear and definite, thereby excluding the type of uncertainty cited in the Action. For example, in *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968), the term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. Similarly, in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. Given this, the term "about two-months" as it is used in the claims may not properly be found to read on 80 days.

In view of the foregoing, removal of the rejection is respectfully requested.

D. Rejection Under 35 U.S.C. §112

Claims 1-8, 10-14 and 30-34 have been newly rejected under 35 U.S.C. §112, first paragraph, as not being enabled by the specification. In particular, it is stated that the working examples in the specification do not show that the PAGs identified are absent about two months post-partum.

In response, Applicants note that the claims are fully enabled. In demonstration of this, Applicants have submitted herewith as Appendix C the Declaration of Dr. Jonathan A. Green. The Declaration describes studies carried out demonstrating that PAGs 4, 6, 7, 16 and 20 are

absent by about two-months post-partum. The studies further describe use of antibodies that immunologically bind these PAGs in maternal serum for early pregnancy detection in accordance with the claims. In the Declaration, Dr. Green outlines studies showing isolation of three monoclonal antibodies binding immunologically to the PAGs. Based on the results, Dr. Green concludes that:

the descriptions in the patent application enable a person of ordinary skill in reproductive biology to, without more than routine experimentation, (a) obtain a sample from a bovine animal, (b) contact the sample with an antibody that binds immunologically to at least one pregnancy associated antigen (PAG), wherein the PAG is present in early pregnancy and absent at about two months post-partum, and (c) detect the PAG bound to the antibody, where the presence of the PAG in the sample indicates that the animal is pregnant.

The information provided therefore establishes enablement for the claimed invention. Routine experimentation is irrelevant to enablement, as the applicable legal standard is undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Examples further need not be presented for every embodiment of an invention. *In re Borkowski*, 164 U.S.P.Q. 624 (CCPA 1970). Given this legal standard and the evidence presented above, it is submitted that the claims are enabled in full compliance with 35 U.S.C. §112, first paragraph. Removal of the rejection is thus respectfully requested.

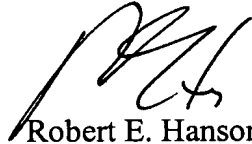
E. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and a notification to that effect is earnestly solicited. Should the Examiner have any questions regarding this response, a telephone call to the undersigned is invited.

PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of one-month to and including August 7, 2003 in which to file the instant response. Pursuant to 37 C.F.R. § 1.17, a check in the amount of \$110.00 is enclosed, which is the process fee for a one-month extension of time. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the instant response, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Account No.: 50-1212/UVMO:003.

Respectfully submitted,



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